Clinical Operations Workgroup
Draft Transcript
September 23, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon, everybody, and welcome to the Clinical Operations Workgroup. This is a public call and there will be opportunity at the end of the call for the public to make comments. Let me do a quick roll call. Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Halamka?

John Halamka – Harvard Medical School – Chief Information Officer
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Chris Chute?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Martin Harris? Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
David Kates?

David Kates – Prematics, Inc. – Vice President Product Management
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Liz Johnson? John Klimek? Wes Rishel? Eric Strom?

Eric Strom – DoD Military Health System – Program Management Support
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Karen Trudel? Don Bechtel?

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Joyce Sensmeier? Lisa Carnahan? Doug Fridsma? Did I leave anyone off? Okay. With that, I'll turn it to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, everybody, for joining this call. Well, this is the Clinical Operations Workgroup and there are two things we wanted to discuss today. I don't think we intend today to come to closure on either one, but we did want to have a discussion on these two issues.

One is the idea that was floated originally by Aneesh Chopra that we should hold a hearing in the Clinical Operations Workgroup to examine the state of standards and the possibility for recommending standards for, as he termed it, remote sensor data in EHRs. Certainly, there are a number of standards, such as those from Continua and IHE, that are used for different devices. At the same time, he noted that many of the current EMRs that are sold by the commercial vendors don't necessarily have capabilities for receiving data in these standards, maintaining it in a consistent and reproducible way and so forth. So there are some issues, I think, to explore there. What I'm going to suggest is that we use this call to try to enumerate some of those issues and then set up a subsequent call with Aneesh to discuss the scope of this possible hearing with him and get some further input towards planning it.

The second issue for this call comes out of not the most recent meeting of the Health IT Standards Committee, but rather, the previous two meetings where we discussed in both of those the problem that needs to be solved of standards for hospital discharge summary. The approach that we recommended that I think was broadly support with some caveats, but that was broadly supported by the Standards Committee, was an approach based on templated CDA for the discharge summary and by extension then into other required document standards, but with that as the first one. I think that the situation that we're in now is that we have the CCD, which is a representation, including the content of the CCR that is a standard that has templated sections that can be reused in the discharge summary. The discharge summary certainly has a need for other templated sections—for example, discharge instructions, discharge medications, some other things—that would be in an inpatient discharge summary that are not in the CCD.

I noted that there was a relatively recently balloted, I think, implementation guide for a discharge summary document that's a final balloted standard in HL-7 as a CDA implementation guide. So I think conceptually the work to be done towards the templated CDA approach generally is to understand the delta or the differences between that CDA implementation guide for discharge summary and the existing adopted standard for the CCD and understand what those differences are in terms of templated sections that we could then recommend to further this direction towards a broader approach to templated CDA documents in the meaningful use program.

Those are the two general areas for discussion on this call. Is there anything else that members want to bring forward or is that unclear as to the scope for this call? Okay.

So hearing none, I'm going to say let's talk actually about the templated CDA approach to the discharge summary first if folks don't mind. This is very fresh in my mind because of the recent discussion in the Health IT Standards Committee about the new standards and interoperability framework and the discussion about NIEM. Some of the discussion there was questioning the relationship of that framework and of NIEM, in fact, to this approach that was agreed to by the committee previously to use templated CDA as essentially the solution to the problem of standards.

Now, from my own thinking, I think it would be nice if the S&I framework and the resources that are being applied in NIEM could approach this problem and could help us, but I'm not sure that we have an entry point into that process for this particular problem. Do others see a different way of approaching that relationship that perhaps I don't see?

John Halamka – Harvard Medical School – Chief Information Officer
Well, let me just start with that. What I heard at the HIT Standards Committee where this was discussed was there was broad support, as you have said, for a modular approach where we wouldn't dictate that there were a specific 20 or 30 kinds of documents that would be represented with CDA implementation guides, but in fact, you could have a finite number of modules that could be combined together as needed by users to create a discharge summary, op note, H&P or other document that would have general

applicability. So really, I think the question is how do we get to the point where we define what the list of components might be and what are the rules of the road for combining these into what is going to be a semantically interoperable, structured document.

So that being a use case, I guess we would for sure have to ask Doug what his advice would be. You wonder if there is a mechanism by which, let's say we look at that whole S&I framework where the SDO participant is HL-7, where the use case is written up as the need to exchange structured summaries of various types and then coming out of that is going to be a set of CDA templates, which are testable in a reference implementation. But as you say, it's all very new, so I'm not sure how we initiate such a process.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes. I had the same question in those, even maybe a more general question, which is if this committee or ONC, by extension, has a need and they want a standard and maybe it's NCPDP or it's HL-7 or it's DICOM, they find a gap. They need something fixed. They need additional standards or an extension or a correction. I don't understand the mechanism to get from the framework as it's been described to are they going to give direction to HL-7. Are they going to contract with HL-7 to do something or—?

John Halamka – Harvard Medical School – Chief Information Officer
Right.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
NCPDP or—?

John Halamka – Harvard Medical School – Chief Information Officer
No. That's a great question, Stan. In fact, I did have a chance to ask Doug about that directly for this particular issue of the templated CDA sections that could be used to assemble a discharge summary. Frankly, he didn't have an answer. I mean he said that he was going to have to think about that, because I think the way that the framework and the process has been described really is certainly applicable to Greenfield problems where you need to start from a problem statement and approach it from first principles. I understand then how that would flow through the process that's been described and develop, potentially, artifacts implemented in multiple different standards, but for something where there is an existing set of standards that needs, as you say, to be extended or adapted in a modular fashion, I have to say I don't understand the relationship yet.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that's a fair statement, so I guess the question for this workgroup is, assuming we can define a process—which would either be done in the context of the HIT Standards Committee or its workgroups or is there something in the S&I framework, like assigning this to the standards harmonization function—it would seem like we want to move forward with doing this. We just need to determine the process for getting the outcome we want.

John Halamka – Harvard Medical School – Chief Information Officer
Right.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And that becomes an ONC issue, I presume.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes. I think that's exactly right, but I mean the underlying concern on my part; and I admit my bias; but I think there is reason, justification for the bias. I mean what you worry is that without saying so that this interoperability framework would become its own standards body and not use the existing standards body to do the work that those bodies actually know how to do.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Right. Well, I mean I think that was acknowledged in the presentation materials from Dr. Fridsma in the last Standards Committee meeting where the issues were listed about compatibility of the artifacts from the S&I framework with the existing standards and infrastructure.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Say more about that because maybe I missed it or didn't understand—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, no. I'm just saying that I think just he listed—and I'm referring back to some of his materials—I'm just looking at it now; some of what he had listed as the challenges and issues to be dealt with was the compatibility of the S&I output with existing health information exchange protocols is the way he put it.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
So more or less, just a recognition then that there is this potential conflict.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. Exactly.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Okay.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So a couple of different alternatives come to mind. One is we could take this as an example to work with the contractors on the S&I framework and seek to move it through the process as an initial test case, if you will, and sort of see how that goes and see how long it takes. Or, I think another alternative, and I think probably just with those of us on the call many of us probably have a degree of comfort—I certainly do—of essentially knowing how to get this work done through the existing standards organizations using the adopted standards and the agreed direction of the Standards Committee. I'm going to say this probably would take no more than a small, single-digit number of months to get it all documented and done and forwarded as a recommendation. So I mean I think we have probably perhaps some comfort with ways of doing this that would be, I think, expeditious and that we, certainly that I have a confidence level in in terms of it working from the standards perspective, but then there's this new framework. I think do we want to use this as a case to sort of test it out or not.

John Halamka – Harvard Medical School – Chief Information Officer
I think you framed that very nicely and the question really for Doug is there's a difference between, say, approaching a Greenfield or a very large, new area of interoperability versus incremental improvement to existing standards, which a single SDO offers.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right and it's not just existing standards. These are the adopted standards in the program.

John Halamka – Harvard Medical School – Chief Information Officer
Yes. So I would think that if we phrase it to Doug that way he might say in this use case, working directly with HL-7 simply to polish existent implementation guides is the right approach versus exercising the NIEM process.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Whereas, the device question may be better put into the NIEM process because it involves IHE and Continua and IEEE and a whole variety of transactions.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Right. It's a case where if we look at a discharge summary again, as an example, and the templated sections of CDA that would be required for that, let's say hypothetically there are ten in the inpatient discharge summary and guess what? Seven of those or 70% of the sections are already fully specified in the CCD and in the existing standards artifacts. In fact, the remainder are already specified in other existing balloted standards and so really, just guidance on how to use them is all that's required. I think that is very different from approaching a problem where, in the first place, there aren't adopted standards yet within this program. There are different potentially competing programs that overlap in terms of their functionality for regulated versus consumer remote devices and it is more of a Greenfield. I think you're exactly right.

John Halamka – Harvard Medical School – Chief Information Officer
So next steps, Jamie, I wonder if the two of us just ask Doug. We have through our workgroup and the discussion in the HIT Standards Committee what we feel is a mandate to get a set of CDA templates in support of structured document formats. Okay with you if we do it through the standard SDO process and for other things that are a Greenfield or a larger multi-disciplinary we'll go through the NIEM process?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. I think that's right. I'm hopeful actually that the S&I framework process and the contractors will work together and essentially figure out how to have entry points for pre-existing standards that need guidance clarification, tweaking, etc., but I think that sounds right to me.

John Halamka – Harvard Medical School – Chief Information Officer
Any folks opposed to such an approach?

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Not here.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, that's really great. John, thank you very much for that. Let's turn then to this medical device and medical device, really, I don't think is completely the right term. I mean I think what we had really said and what I heard from Aneesh originally was sensor data, meaning remote patient data from a variety of devices, but that could be in all kinds of different settings, so in potentially in-patient, home and other settings. I think it really is intended to cover the full range of different kinds of devices that remotely connect to the EMR.

I think the question perhaps that we'd want to start with is how would we, if we were going to hold a hearing to seek input on framing this issue in order to run it through the S&I process, how would we define that? I want to perhaps start with the scoping question of is the right scope any remote patient data.

John Halamka – Harvard Medical School – Chief Information Officer
Remember the work that was done in HITSP on this and then some work that was done in IEEE and Continua. It first asked in use cases what would this look like where one use case would be I have many devices in my home. They go to a hub and then the hub goes to an EHR or a PHR. So basically what are we talking here? A device that goes to an EHR directly? Is there a hub involved? What is the architecture? Therefore, there are different standards, depending on how you might define the use case. What does a sensor mean? Is that a glucometer? Is that a pulse oximeter, a blood-pressure cuff, a bathroom scale, etc.?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
A refrigerator. Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Yes. Right. To give you a case example for me: I was testing out this Withings Scale, which is a Wi-Fi scale that sends an XML construct in a proprietary fashion to the company and then the company

enables you to link the data into Google and Microsoft APIs. So when I step on the scale every morning, ten milliseconds later it's in my Google health record without any intervention by me.

The problem with that is if Withings, as a company, goes out of business I have to throw away my scale. There is no mechanism or standard that would enable me to route data directly to an EHR or PHR. I have to go through the company's proprietary approach.

So that's an example of a use case to solve and take through the NIEM process. How might you get a bathroom scale, which would have user configurability that enables you to sure go through an intermediary, like a manufacturer site, but if you want to do SMTP directly to an NHIN Direct recipient you should be able to.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right.

John Halamka – Harvard Medical School – Chief Information Officer
So I think it starts with, as the NIEM process suggests, setting up some of these use cases and maybe as we hold hearings we bring in IEEE, Continua, folks who worked on this in the past to help us frame up some of those use cases to hand to NIEM.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that's very good advice. So that would say we should really use the hearing to gather input, I think then, on the highest priority use cases.

John Halamka – Harvard Medical School – Chief Information Officer
I mean that's a thought, because if we jumped ahead to the standards I guess the question is what problem are we trying to solve.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. That's a very good point. So going back to the problem statement, it's not just about having essentially messaging standards or methods between the end points, but it's also about having EMR or EHR functionality in the certified products that is able to capture, manage and reproduce such data in consistent ways.

David Kates – Prematics, Inc. – Vice President Product Management
Right. I mean the question is where in the infrastructure do you put the level of abstraction so that you're not inundating the provider with byte-by-byte detail that they're not interested in. I don't know that we want to be dictating an architecture in that regard, but presumably, that abstraction level needs to exist.

John Halamka – Harvard Medical School – Chief Information Officer
All right. A question too would be as we think about the sensor communication directly to an EHR, given that the source of the data is not coming from maybe an FDA approved device, I remember back in the HITSP days we talked about differing use cases and differing standards depending on the nature of the generator of the data, from whom, on what device, for what purpose. Is it something like consumer sourced weight data or is it something like a ventilator? So having to figure out the meta data around this and the abstraction layers, as you mentioned, is important.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Good. Well then, it sounds like we are rapidly coming to agreement on a general approach for these two different problems. In fact, the hearing that we would contemplate having on the various problems of the remote sensor data would be one that really would be done in conjunction with the appropriate contractors in the S&I framework, as well as ONC. So it would seem that perhaps our next step would be, as you said, John, to approach Doug and then discuss this with him. In fact, I would suggest we would reconvene this workgroup with the appropriate contractor or contractors in that process to do the planning for the hearing.

John Halamka – Harvard Medical School – Chief Information Officer
Sounds very reasonable to me. The standards harmonization would be Deloitte, for example. I think they are also on use case, if I recall.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right.

John Halamka – Harvard Medical School – Chief Information Officer
So getting the Deloitte team involved would probably make a lot of sense.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. Okay. So, is there anything about this approach then that gives anybody the willies in terms of really charging forward through the pre-existing standards of the standards organization with the adopted standards for the document, simply the document problem starting with discharge summary and then taking the new problems essentially through the S&I framework?

John Halamka – Harvard Medical School – Chief Information Officer
It certainly sounds good to me.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, this was a very efficient call.

John Halamka – Harvard Medical School – Chief Information Officer
Yes. Nobody is objecting to anything. I mean this is harmony. It must be the weather.

Judy Sparrow – Office of the National Coordinator – Executive Director
Let's see what the public has to say. Operator, do you want to check and see if we have any public comment, please?

Moderator
Yes.

Judy Sparrow – Office of the National Coordinator – Executive Director
Jamie, while we're waiting: I guess you'll talk to Doug and then we'll have to set up another meeting date for this group?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. Exactly. And we'll want to do that in conjunction probably with Deloitte.

Judy Sparrow – Office of the National Coordinator – Executive Director
Right. Got it. Okay.

Moderator
Our first comment is from Fred Buhr with Metasteward. Please proceed with your comment.

Fred Buhr – Metasteward
This is Fred Buhr with Metasteward. Essentially, I am participating in a number of workgroups in HITSP and also in HL-7 relating to the Personal Healthcare Record Workgroup and I just wanted to endorse Dr. Halamka's view in the view that this workgroup is accepting at this point. I'm totally from a user standpoint and not representing any company or anything else, just purely from a user standpoint. Anyway, thank you very much for looking at the problem in this way.

Judy Sparrow – Office of the National Coordinator – Executive Director
Any other comments?

Moderator

We don't have any more public comments at this time.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much. Thank you, Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, Judy. Thank you, John and everybody who has joined this call. I appreciate your time here today and, as always, we're available by e-mail for any communications on this. So, John, I think our next steps are for the two of us to talk to Doug and then, as Judy said, we'll reconvene this workgroup.

Judy Sparrow – Office of the National Coordinator – Executive Director
Good. All right.

John Halamka – Harvard Medical School – Chief Information Officer
Okay. Thank you very much. You guys have a good day.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much, everybody.